



9-12-05

IFW

Commissioner for Patents
P.O.Box 1450
Alexandria, VA 22313-1450

September 8, 2005

Re: Application #10/675,722

Attn: David Vanic,
Examiner

We would like to thank you for the assistance you have provided in this rather unique application. We realize is very brief in the details but feel the uniqueness warrants brevity.

To avoid some of the confusion we may have created, I will summarize our application. What we have is an extruded starch polymer foam, completely biodegradable and water soluble. The foam is extruded by KTM Industries using a formulation appropriate to our needs. The foam is used by itself serving as a lattice, slowly filling with fluid from the wound site forming an effective barrier and assisting healing. It is ideal for treatment of severe wounds that require often replacement. Although the lattice can remain intact for several days, due to cost and convenience it can, without patient discomfort, be removed by extraction or simple on-site swabbing or rinsing and replaced once or several times a day. The dressing can readily be disposed of by rinsing down any convenient drain. To date, numerous units have been tested on volunteer subjects with excellent success.

In response to your office action, we have clarified claim 2 by replacing the word molecule with the more appropriate word polymer. We accept your rejection of claim 3 if we are unable to add a description of this feature to the text (line 12-13, page 3).

For claims 1, 2, 4 & 5, we are aware of the brevity of the application and the claims, however, we know of no prior usage where an extruded biodegradable water soluble foam is used by itself to absorb fluid and create a gel to constitute a dressing.

In reviewing the cited art, we would like to point a confusion in the term biodegradable, as it is used and misused with regularity. To relieve some of this confusion, the ASTM has proposed placing restrictions on the % of a material that will completely degrade within a reasonable time frame. In an effective time frame for these applications, the percentages run from 80 to 90%. Our material approaches 100%.

The art cited in Patent 5,009,648 describes the use of a starch constituting from 5% to 50% blended in a polymeric film for use in medical devices such as ostomy pouches. To technically use the term biodegradable, the total content should be from 80 to 90% degradable. In reality, it is only partially biodegradable. Blending their starch with synthetic polymers significantly reduces further the biodegradable content of the device. The device simply is not a starch polymer; the outer film is a blended composite with synthetic polymeric material. Additionally, it is not a dressing nor could it serve as one. The inner water resistant lining is synthetic and the outer starch containing film helps make the device more disposable, and when a tissue like material is attached to the outer side, makes it more comfortable to wear. The device is flushable but must be further long-time degraded in a septic system, compost pile or landfill.

In contrast, our device is an extruded starch polymer, functions as a dressing when moisturized, is fully biodegradable and can be removed from the application site by rinsing with water and completely disposed using normal sewage access.

The art cited in Patent 5,741,521 describes a method for producing a matrix of an amylaceous (biodegradable) starch material in association with synthetic (non-biodegradable) polymer under elevated temperature and pressure. The resulting matrix typically contains only a few % by weight of amylaceous material which is the only biodegradable part and that part contains an active agent which is released as the degradation slowly occurs. The major art of the device is that it is useful for the controlled release of active agents, primarily for agricultural applications.

The device is not, nor can it serve as, a dressing. The biodegradable portion by itself is a starch paste bonded in an association with a synthetic polymer and has none of the essential characteristics of an effective dressing. The device in our application is a true biodegradable starch polymer extruded into a foam sheet, which serves excellently as a dressing.

The art cited in Patent 5,534,561 describes an adhesive composition suitable for wound dressing. It is not foam, not a gel, and not degradable, let alone biodegradable. There are dispersions of degradable portions which may carry pharmaceutical agents for dispensation directly to the wound site. These small limited regions do not make the dressing degradable.

The art cited in Document 2002/0122771 describes a dressing in the form of a gel over the wound. In general the polymerizing ingredients are sprayed into the wound and the gel forms in situ, however, it can be polymerized and the gel formed externally. The created gel is not biodegradable and typically contains significant synthetic components. There are claims only of degradability. The only reference to biodegradability is in paragraph 25 where the non-biodegradability of their device is recognized and, where desired, can be approximated by using a very thin hydrogel coating which, although not biodegradable, will degrade more readily. It is difficult to envision how such a wound covering could serve effectively as a dressing.

In contrast, our application describes a dressing consisting of the preformed foam of a biopolymer which serves as a lattice for absorption of fluid from the wound, sufficient to form an effective wound healing barrier. While they describe a classic hydrogel we have a gel-like moisturized foam lattice. The foam is created by extrusion, is fully biodegradable and sufficiently soluble as to be removed by rinsing and is completely disposable using normal sewage access.

We trust that this response will be sufficient to fully evaluate our claims. If any more information is needed, please contact the undersigned. Thank you for your consideration this matter.

Respectfully,

A handwritten signature in black ink, appearing to read "John F. Holland", with a stylized flourish at the end.

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